K120955

DEC 17 2012

510(k) SUMMARY (as required by 21 CFR 807.92)

Columbus Total Knee System AS
December 17, 2012

COMPANY: Aesculap® Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Julie Tom Wing
800-234-9179 (phone)
610-791-6882 (fax)
julie.tomwing@aesculap.com (email)

TRADE NAME: Columbus Total Knee System AS

COMMON NAME: Total Knee System

CLASSIFICATION NAME: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

REGULATION NUMBER: 888.3560

PRODUCT CODE: JWH

SUBSTANTIAL EQUIVALENCE

The Columbus Total Knee System Alternate Surface (AS) is substantially equivalent to Aesculap's Columbus Total Knee System (K071220) and the previously cleared Columbus Total Knee System (CRA/PSA) (K053390).

DEVICE DESCRIPTION

The Columbus Total Knee System AS includes both "Cruciate Retaining" (CR) and "Posterior Stabilized" (PS) variants of the femoral and tibial components for cemented use with the previously cleared UHMWPE Columbus tibial inserts and patellae. The tibial hemi-spacers (wedges) are the same design as the previously cleared Columbus Total Knee System (CRA/PSA) (K053390). All components manufactured from CoCrMo are coated with a ZrN (Zirconium nitride) coating which has been cleared in Aesculap Columbus AS Knee submission (K071220).

INDICATIONS FOR USE

The Columbus Total Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

The Columbus Knee is designed for use with bone cement.

TECHNOLIGICAL CHARACTERISTICS (compared to Predicate(s))

The base materials used for the new Aseculap implants are the same as that used to manufacture the predicate Aesculap devices. The only differences are a line extension introducing narrow CR and PS femurs and an introduction of AS coated tibial hemi-spacers including a smaller size (0/0+) hemi-spacer.

The Columbus narrow femurs are a dimensional modification that is available in right and left configurations in sizes that fall within the size range of femoral components previously cleared in Columbus AS Total Knee System (AS) (K071220).

The AS coated tibial hemi-spacers are a design change to the previously approved hemi-spacers cleared in K053390. The smaller size (0/0+) hemispacer is designed to mate with the same standard size or respective plus-size trays (i.e. T0 wedge/T0+ tibial tray). The AS coating was cleared previously in K071220.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable.
Design verification of the Columbus Total Knee System AS was performed as a result of the risk assessment which were determined to be substantially equivalent to the predicates.

510(k) SUMMARY (as required by 21 CFR 807.92)

EnduRo Knee System
December 17, 2012

COMPANY: Aesculap® Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Julie Tom Wing
800-234-9179 (phone)
610-791-6882 (fax)
julie.tomwing@aesculap.com (email)

TRADE NAME: EnduRo Knee System

COMMON NAME: Total Knee System

CLASSIFICATION NAME: Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer

REGULATION NUMBER: 888.3510

PRODUCT CODE: KRO

SUBSTANTIAL EQUIVALENCE

The EnduRo Knee System is substantially equivalent to previously cleared, Aesculap Implant Systems EnduRo Knee System (K101815).

DEVICE DESCRIPTION

The EnduRo Knee System is a cemented prosthesis with a rotating hinge design. The femoral component, tibial plateau and extension stems are manufactured from CoCrMo. The tibial "gliding surfaces" (insert) and patella are manufactured from UHMWPE. The tibial mask is made from PEEK Optima® (LT1). The axial sleeve and femoral bushing components are produced from PEEK Optima® (LT1CA30). The system is made up of numerous components available in various sizes. The femoral, tibial plateau, and extension stems are also available with a ZrN (Zirconium nitride) coating. All components are sterile and for single use only.

INDICATIONS FOR USE

The EnduRo Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

Hinge knee systems are designed for use in patients in primary or revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments are absent or insufficient. The femoral and tibial augments are to be attached to their respective components with a fixation screw or screws.

The EnduRo Knee System is intended for cemented use only.

TECHNOLIGICAL CHARACTERISTICS (compared to Predicate(s))

The base materials used for the new Aseculap implants are the same as that used to manufacture the predicate Aesculap devices. The only difference is a design modification to the locking nut.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable.
Mechanical testing to evaluate the resistance against loosening of the screw connection of the tibia component and the tibia locking ring of Aesculap EnduRo Knee System was performed for 5 million cycles. Results were found to be substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Aesculap Implant System, LLC
% Ms. Julie Tom Wing
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Letter dated: December 17, 2012

Re: K120955
Trade/Device Name: COLUMBUS Total Knee System AS and EnduRo Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JWH, KRO
Dated: December 13, 2012
Received: December 14, 2012

Dear Ms. Tom Wing:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosures) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number:_____

Device Name: Columbus Total Knee System AS

Indications for Use:

The Columbus Total Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

The Columbus Knee is designed for use with bone cement.

Prescription Use ____X____ and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120955

A. INDICATIONS FOR USE STATEMENT

510(k) Number:_____

Device Name: EnduRo Knee System

The EnduRo Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

Hinge knee systems are designed for use in patients in primary or revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments are absent or insufficient. The femoral and tibial augments are to be attached to their respective components with a fixation screw or screws.

The EnduRo Knee System is intended for cemented use only.

Prescription Use ___X___ and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Orthopedic,
and Restorative Devices

510(k) Number K 120955